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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,898	08/22/2003	Joar Opheim	03-109	1343
23843	7590	12/12/2006		
FOOTHILL LAW GROUP 777 N. FIRST STREET, SUITE325 SAN JOSE, CA 95112			EXAMINER GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary**Application No.**

10/646,898

Applicant(s)

OPHEIM, JOAR

Examiner

Isis A. Ghali

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and declaration, both filed 09/25/2006.

Claims 10-13 have been cancelled, claims 1-9 are pending and included in the prosecution.

The following new ground of rejection is necessitated by applicant's amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 as amended has introduced new matter because nowhere in the specification applicant has disclosed that the "flavoring is present at a concentration greater than 0.2%". On page 3, lines 15-16, and page 6, lines

Art Unit: 1615

17 and 18, applicant disclosed that the "about 1 part by weight of the water soluble flavoring". The specification has not support for "flavoring is present at a concentration greater than 0.2%" with open ended upper level that can amount to up to 100%. On page 5, lines 23-25, applicant disclosed 0.5% of specific flavoring agent Firmenich #52311A, and not for any flavoring agent in general.

The following rejection has been discussed in the previous office action, and is maintained for reasons of record:

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachman et al. in combination with US 5,955,102 ('102).

Lachman teaches a capsule shell comprising gelatin, plasticizer, water and flavor. The amount of plasticizer is calculated to be 40-60% and chosen according to the end use of the capsule and the effect of capsulated material on the shell. The amount of water is calculated to be 70-130% but water is lost during drying process. The flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule (page 407, right column).

Lachman does not teach the claimed amount of the water and plasticizer, or fish oil as a dietary supplement.

However, Lachman suggested that plasticizer is chosen according to the end use of the capsule and the effect of capsulated material on the shell, and this teaching would have motivated one having ordinary skill in the art to adjust the amount of plasticizer according to the intended use and encapsulated material.

Additionally, Lachman teaches that the water is lost during drying process, i.e. the amount is expected to be radically reduced below 70%. Note that applicant discloses in page 6 of the specification, lines 1-2, that the amount of water present in the shell is 10-45%, and that amount is reduced to 8+/-2% after drying of the capsule. The reference does not disclose if the amount before drying or after drying.

In any event, the amount of water and plasticizer do not impart patentability to the claims, absent evidence to the contrary.

Fish oil is well known dietary supplement, and also known to be provided in a gelatin capsules.

US '102 teaches fish oil is preferably provided in a gelatin capsule (abstract; col.2, lines 31-36).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the gelatin capsule disclosed by Lachman that comprises gelatin, softener, water and small amount of flavor and use the capsule to deliver fish oil disclosed by US '102, motivated by the teaching of US '102 that the gelatin capsules are the preferred delivery method for the fish oil, with reasonable

Art Unit: 1615

expectation of having a gelatin capsule comprising shell containing 1% of flavoring agent to impart the desired taste as disclosed by Lachman to deliver fish oil to the patient in need with great success.

Response to Arguments

5. Applicant's arguments filed 09/25/2006 have been fully considered but they are not persuasive. Applicant argues that Lachman does not teach the claimed amount of water of 6-10% or flavoring more than 0.2%. Applicant had shown criticality of the amount of water in the shell by the declaration filed 04/10/2006. No suggestion to modify Lachman reference to achieve the present concentration of water and flavoring. The present invention shown commercial success by the declaration filed 09/25/2006, not shown by any prior art or Lachman reference that has been available since 1976.

In response to this argument, it is noticed that Lachman disclosed two different flavoring such as vanillin that is present in amount of 0.1% and the second is essential oils that does not exceed 2% to impart desirable odor to the capsule or for taste purpose. Therefore, Lachman disclosed flavoring agent not exceeding 2%, which meets the limitation of "greater than 0.2%" as instantly claimed. Essential oils are disclosed as taste improving agent and read on the flavoring agents, absence of claiming any specific flavorings.

The declaration filed on 04/10/2006, as discussed in the previous office action, was insufficient to overcome the rejection of claims 1-9 based upon 35 U.S.C. 103 (a) as set forth in the last Office action because: there was no showing that the objective

Art Unit: 1615

evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. The scope of the claims is broad covering all flavors in any amounts greater than 0.2%, while the declaration is limited only to one flavor Firmenich #52311A, at specific concentration 0.5 to 1.0% of the flavoring agent in relation to the amount of water of 6-10%. Additionally, applicant declares that below 0.5% flavoring agent gives distorted flavor and above 1.0 it gives harsh taste, so no support for the claimed amount "greater than 0.2%". The solubility of the flavoring agents in water may vary. The species of the flavoring agent in specific concentration in the shell composition that is soluble in a specific amount of water of the declaration does not support the generic concept of the claims.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one having ordinary skill in the art at the time the invention was made would have provided the gelatin capsule disclosed by Lachman that comprises gelatin, softener, water and small amount of flavor and use the capsule to deliver fish oil disclosed by US '102, motivated by the teaching of US '102 that the gelatin capsules are the preferred delivery method for the fish oil, with reasonable expectation of having a gelatin capsule comprising shell

Art Unit: 1615

containing flavoring agent to impart the desired taste as disclosed by Lachman to deliver fish oil to the patient in need with great success.

Regarding commercial success, it does not overcome the obviousness rejection. The claims encompass the flavored gelatin capsule disclosed by Lachman because the claims encompass the flavoring agent disclosed by Lachman.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali